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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,547	12/09/2003	Andrzej J. Chanduszko	106586-154 US2	4546

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EXAMINER	
POUS, NATALIE R	
ART UNIT	PAPER NUMBER
3731	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	05/01/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 05/01/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/731,547	CHANDUSZKO ET AL.	
	Examiner	Art Unit	
	Natalie Pous	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/4/05,7/6/04,5/24/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-24 have been considered but are moot in view of the new ground(s) of rejection based on amendments to the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 2, 6 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Palestrant (US 4425908).

Regarding Claim 1, Palestrant teaches an apparatus comprising: a device capable of use as a patent foramen ovale (PFO) closure device having a deployed configuration (fig. 1) for providing compressive force to septum primum and septum secundum and including: a central body (42) for extending through the PFO, wherein the central body is elongated and substantially linear and extends along a longitudinal axis of the device, a first end cap (40), and first and second loops (each formed of wire 20, see fig. 2) on one side of the PFO, each of the first and second loops extending from the central body to the first end cap (fig. 1), each of the first and second loops defining a plane substantially parallel to septum primum and septum secundum such that the first and second loops apply a force, perpendicular to the plane, to one of septum primum and septum secundum.

Regarding Claim 2, Palestrant teaches the apparatus of claim 1, further comprising, on the other side of the PFO, a plurality of struts (51) extending radially from the central body (fig. 1) and having ends capable of contacting one of septum primum and septum secundum.

Regarding Claim 6, Palestrant teaches the apparatus of claim 1, wherein the device has a collapsed configuration for delivery through a catheter (fig. 4a).

Regarding Claim 23, Palestrant teaches an apparatus comprising: a device capable of use as a septal defect closure device having a deployed configuration capable providing compressive force to septum primum and septum secundum

secundum and including: a central body (42) for extending through the defect, wherein the central body is elongated and substantially linear and extends along a longitudinal axis of the device, a first end cap (40), and first and second loops (formed of wires 20) on one side of the defect, each of the first and second loops extending from the central body to the first end cap, each of the first and second loops defining a plane substantially parallel to septum primum and septum secundum such that the first and second loops apply a force, perpendicular to the plane, to one of septum primum and septum secundum.

Claims 1, 3-7, 9, 10, 14-19, 23 and 24 rejected under 35 U.S.C. 102(e) as being anticipated by Freudenthal et al. (US 7097653).

Regarding Claim 1, Freudenthal teaches an apparatus comprising: a patent foramen ovale (PFO) closure device having a deployed configuration (fig. 13) for providing compressive force to septum primum and septum secundum and including: a central body (26) for extending through the PFO, wherein the central body is elongated and substantially linear and extends along a longitudinal axis of the device, a first end cap (fig. 13), and first and second loops (each formed of wire 2, see fig. 13) on one side of the PFO, each of the first and second loops extending from the central body to the first end cap (fig. 13), each of the first and second loops defining a plane substantially parallel to septum primum and septum secundum such that the first and second loops apply a force, perpendicular to the plane, to one of septum primum and septum secundum.

Regarding Claim 3, Freudenthal teaches the apparatus of claim 1, further comprising, on the other side of the PFO, a second end cap (fig. 13), and third and fourth loops on one side of the PFO (2), each of the third and fourth loops extending from the central body to the first end cap and second end cap, each of the third and fourth loops defining a plane substantially parallel to septum primum and septum secundum such that the first and second loops apply a force, perpendicular to the plane, to one of septum primum and septum secundum (fig. 13).

Regarding Claim 4, Freudenthal teaches the apparatus of claim 3, where there are three or more loops on each side of the PFO (fig. 13).

Regarding Claim 5, Freudenthal teaches the apparatus of claim 3, wherein the central body (26) and the first and second end caps are oriented in a line substantially perpendicular to septum primum and septum secundum (fig. 13).

Regarding Claim 6, Freudenthal teaches the apparatus of claim 1, wherein the device has a collapsed configuration for delivery through a catheter (Column 3, proximate lines 1-14).

Regarding Claim 7, Freudenthal teaches the apparatus of claim 6, wherein the device includes nitinol (Column 7, proximate lines 28-30).

Regarding Claim 9, Freudenthal teaches the apparatus of claim 6, wherein the device is made from a shape memory material with properties such that the device, when delivered into a body has a phase transition and assumes the deployed configuration (it is noted that nitinol inherently has a phase transition when deployed)

Regarding Claim 10, Freudenthal teaches the apparatus of claim 1, wherein the device is retrievable, redeployable, and repositionable (see entire document, for example Column 9, proximate lines 3-17).

Regarding Claim 23, Freudenthal teaches an apparatus comprising: a device capable of use as a septal defect closure device having a deployed configuration capable providing compressive force to septum primum and septum secundum secundum and including: a central body (26) for extending through the defect, wherein the central body is elongated and substantially linear and extends along a longitudinal axis of the device, a first end cap (fig. 13), and first and second loops (formed of wires 2) on one side of the defect, each of the first and second loops extending from the central body to the first end cap, each of the first and second loops defining a plane substantially parallel to septum primum and septum secundum such that the first and second loops apply a force, perpendicular to the plane, to one of septum primum and septum secundum.

Regarding Claims 14, 15, 16, 17, 18, 19 and 24 Freudenthal teaches a method comprising delivering the PFO closure device of claims 1, 2, 3, 4, 10 and 23 through a catheter (Column 9, proximate lines 3-17) to a PFO (Column 9, proximate lines 40-45), and further teaches wherein the device includes a shape memory material (Column 7, proximate lines 27-33).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Freudenthal in view of Rulz (US 5976174). Freudenthal teaches all limitations of preceding dependent claim 1, and further teaches wherein the device is formed of a shape memory material, but fails to teach wherein the device includes a shape memory polymeric material. Rulz teaches a septal closure device wherein the device is formed of a shape memory polymeric material. It would have been an obvious matter of design choice to form the device of Freudenthal with a shape memory polymer as taught by Rulz since applicant has not disclosed that a polymer provides any advantage over Nitinol, and it appears that both materials perform the task of actuating to a second configuration when deployed in the body equally well.

Claims 11, 13 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freudenthal in view of Huebsch et al. (US 6117159)

Freudenthal teaches all limitations of preceding dependent claim 1 but fails to teach wherein material is present over the first and second loops for promoting tissue ingrowth. Huebsch teaches a septal defect closure device wherein the device is bioresorbable covered in a material to promote tissue ingrowth in order to help with stabilization of the device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Freudenthal with a material to promote tissue ingrowth in order to help with stabilization of the device.

Claims 12, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Freudenthal and Huebsch, and further in view of Neuss et al (US 6355052). The combination of Freudenthal and Huebsch teaches all limitations of preceding dependent claims 1 and 11, and further teaches delivering the closure device through a catheter to PFO, and drawing the device back into the catheter for repositioning (see Freudenthal above), but fails to teach wherein the loops are made of a bioresorbable material. Neuss teaches a PFO closure device, wherein the loops are made of a bioresorbale material such to avoid complications associated with permanently implanted foreign bodies. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Freudenthal and Huebsch as with bioabsorbale material such to avoid complications associated with permanently implanted foreign bodies.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
4/16/07

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SUPERVISORY PATENT EXAMINER
4/24/07